



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Use of Scopolamine to Treat Depression.

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to Antares Pharma Inc., a company having a place of business in Ewing, New Jersey, to practice the inventions embodied in the following patent applications and patents:

1. U.S. Patent Application 11/137,114, filed May 25, 2005, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-US-01];
2. European Patent 1896025, issued December 28, 2011, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-EP-03];
3. German Patent 1896025, issued December 28, 2011, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-DE-07];
4. French Patent 1896025, issued December 28, 2011, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-FR-08];
5. British Patent 1896025, issued December 28, 2011, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-GB-09]; and
6. Canadian Patent Application 2610025, filed May 18, 2006, titled "Scopolamine for the Treatment of Depression and Anxiety" [HHS Ref. No. E-175-2004/0-CA-04]

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Exclusive Patent License may be worldwide, and the field of use may be limited to: "The use of scopolamine for treatment of

depression, including major depressive disorder, wherein the route of administration is subcutaneous, intramuscular, or transdermal delivery such as through injection or a patch or topical gel-based product”. This announcement is the second notice to grant an exclusive license to this technology.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patents, patent applications, inquiries, comments, and other materials relating to the contemplated Exclusive Patent License should be directed to: Betty B. Tong, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 594-6565; Facsimile: (301) 402-0220; E-mail: tongb@mail.nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The subject invention describes the use of scopolamine for the treatment of depression, including major depressive disorders (MDD). Although scopolamine has been employed in the treatment of nausea and motion sickness, the suitability of scopolamine for treating MDD was unrecognized prior to this invention. Current MDD treatments can be ineffective in a large percentage of patients and typically do not take effect until 4 weeks after administration. In contrast, treatment with scopolamine has

a wide-ranging and rapid effect, suggesting it can be effective either as a standalone treatment or as a treatment for patients who are unresponsive to currently available drugs.

The prospective Exclusive Patent License will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective Exclusive Patent License may be granted unless within thirty (30) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License. Comments and objections submitted in response to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

August 22, 2013
Date

Richard U. Rodriguez,
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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